

Vladeck, Ph.D., Bruce C.
New York, NY

May 4, 2007

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

-----X MDL NO. 1456
IN RE: PHARMACEUTICAL INDUSTRY : CIVIL ACTION:
AVERAGE WHOLESALE PRICE LITIGATION : 01-CV-12257-PBS
-----X

THIS DOCUMENT RELATES TO: :
U.S. ex rel. Ven-A-Care of the : CIVIL ACTION:
Florida Keys, Inc. v. Abbott : 06-CV-11337-PBS
Laboratories, Inc. :
-----X

IN THE CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA

-----X
STATE OF ALABAMA, : CASE NO.
Plaintiff, : CV-05-219
v. :
ABBOTT LABORATORIES, INC., : JUDGE
et al., : CHARLES PRICE
Defendants. :
-----X

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202-220-4158

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<p>1 a.m. We're going back on the record, continuing 2 with Tape No. 2. 3 Q. Dr. Vladeck, during the break I handed 4 you a copy of what we've previously marked in 5 another deposition as Exhibit Abbott 038. It's a 6 two-page document that was produced to us by -- 7 by the government. You see the Bates numbers at 8 the bottom, HHD 008. 9 The first page of Exhibit Abbott 038 is 10 what appears to be a photocopy of 42 CFR Section 11 405.517, as it was enacted in January of 1992, 12 and before it was amended in 1998, which is -- as 13 I gave to you mistakenly earlier as Exhibit 14 Abbott 153. 15 Have you had a chance to take a look at 16 -- at the first page of that exhibit? 17 A. I have. 18 MS. BROOKER: I just interpose just an 19 objection to the characterization. It may or may 20 not be accurate. I'm just not sure. But you can 21 go ahead and proceed. 22 Q. Any reason to believe that this is not</p>	<p>1 the methodology for paying for Part B drugs that 2 was in place from after the implementing 3 regulations for over 90 were adopted until the 4 regulations implementing the relevant provisions 5 of the Balanced Budget Act were adopted in 1998. 6 Q. And so, for the entire time that you 7 were administrator of HCFA, from May of 1993 8 until September of 1997, this regulation would 9 have described how Medicare Part B reimbursed 10 providers for certain drugs that were 11 reimbursable under Medicare Part B. Correct? 12 A. That's -- that's my -- 13 MS. BROOKER: Objection. Form. Sorry. 14 Go ahead. 15 THE WITNESS: Sorry. 16 A. That -- that's my understanding, yes. 17 Q. If you could look to Part B of -- of 18 this particular regulation, 405.517, it reads 19 that: 20 "Payment for a drug described in 21 Paragraph A should be based on the lower of two 22 measurements."</p>
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<p>1 an accurate copy of -- of that regulation? 2 MS. BROOKER: Objection. Form. 3 A. It looks to me like -- no, there's no 4 reasoning. 5 MR. BREEN: I would only interpose an 6 additional objection. I don't think it's 7 complete. I think this regulation scheme has -- 8 has definitions or different sections and things 9 like that. So, I would only interpose that -- 10 that technical objection. 11 MR. COOK: Okay. 12 Q. You understand that the Code of Federal 13 Regulations is a very long document. 14 Correct? 15 A. I'm familiar with it, yes. 16 Q. And that it includes more than just 17 this one page? 18 A. Yes, sir. 19 Q. If you could describe for me, what do 20 you understand 405.517 to relate to? 21 MS. BROOKER: Objection. Form. 22 A. My understanding is that this describes</p>	<p>1 Correct? 2 A. That's correct. 3 MS. BROOKER: Objection. Form. 4 Q. Could you tell me what are the two 5 measurements that this regulation provided for as 6 the alternatives for paying for Part B drugs? 7 MS. BROOKER: Objection. Form. 8 A. The alternatives were either actual 9 acquisition cost or average wholesale price. 10 Q. The phrase here "national average 11 wholesale price of the drug," do you see that? 12 A. Yes, sir. 13 Q. Is it your understanding that during 14 the approximately four years, or just over four 15 years that you were administrator of HCFA, that 16 to the extent that Medicare Part B paid for drugs 17 based upon the average wholesale price of the 18 drugs, that they did so based upon published 19 average wholesale prices? 20 A. Yes, that was my understanding. 21 Q. And just some -- some basics of -- of - 22 - of how this regulation works. To whom is this</p>

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<p>1 regulation addressed?</p> <p>2 MS. BROOKER: Objection. Form.</p> <p>3 A. This regulation is addressed, as a</p> <p>4 practical matter, largely to the Medicare</p> <p>5 carriers, the contractors who administer Part B</p> <p>6 payments.</p> <p>7 Q. So, this would be the formal means by</p> <p>8 which Medicare instructs its carriers on how they</p> <p>9 should administer the program?</p> <p>10 MS. BROOKER: Objection. Form.</p> <p>11 A. Actually, I'm -- although I don't know</p> <p>12 the specifics in this instance, in general, there</p> <p>13 would likely have been more specific and detailed</p> <p>14 instructions to carriers interpreting, expanding</p> <p>15 upon, talking about technical applications issues</p> <p>16 associated with this regulation, but it would be</p> <p>17 based upon this part of the regulations.</p> <p>18 Q. And when you became -- strike that.</p> <p>19 The other methodology for payment under</p> <p>20 Section 405.517 is the estimated acquisition</p> <p>21 cost. Does the regulation describe how one would</p> <p>22 determine what the estimated acquisition cost of</p>	<p>1 MS. BROOKER: Objection. Form.</p> <p>2 A. Yes.</p> <p>3 MR. COOK: And then I'd like to show</p> <p>4 you what was previously marked as Exhibit Abbott</p> <p>5 120. I'll have the court reporter hand it to</p> <p>6 you. If you could take a look at that while I'm</p> <p>7 flipping to my copy of it.</p> <p>8 And for the record, that is a copy of</p> <p>9 relevant pages from the June 5, 1991, Federal</p> <p>10 Register.</p> <p>11 When we marked this in a previous</p> <p>12 exhibit, we all agreed that because the Federal</p> <p>13 Register is publicly published, we didn't need to</p> <p>14 include the hundreds of pages that this</p> <p>15 particular proposed regulation had and -- and put</p> <p>16 in the record only Pages 25800 and Pages 25801,</p> <p>17 and a couple of pages around it, rather than the</p> <p>18 entire -- entire document.</p> <p>19 MS. BROOKER: If I could just interpose</p> <p>20 an objection, though, just for the record.</p> <p>21 It's a proposed rule. No. 1, I just</p> <p>22 want to clarify that. And -- and I just object</p>
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<p>1 the drug would be?</p> <p>2 MS. BROOKER: Objection. Form.</p> <p>3 A. I don't believe that was described in</p> <p>4 the regulation.</p> <p>5 Q. Okay. Actually, the next sentence, I</p> <p>6 think, describes -- you know, I'll just read it.</p> <p>7 A. That is correct. No, that is correct.</p> <p>8 Q. Yes. Let me just read it and then we -</p> <p>9 - I should have done that at the beginning. I</p> <p>10 apologize. I'll just read it.</p> <p>11 "The estimated acquisition cost is</p> <p>12 determined based on surveys that the actual</p> <p>13 invoiced price is paid for the drug."</p> <p>14 And then the next sentence reads:</p> <p>15 "In calculating the estimated</p> <p>16 acquisition cost of a drug, a carrier may</p> <p>17 consider factors such as inventory, waste, and</p> <p>18 spoilage."</p> <p>19 Is that an accurate description of what</p> <p>20 you understood the estimated acquisition cost to</p> <p>21 be between 1993 and 1997 for purposes of -- of</p> <p>22 this regulation?</p>	<p>1 to the extent that it is only a portion of the</p> <p>2 Federal Register Notice. And so, Dr. Vladeck</p> <p>3 will not have access to -- to the entirety of it,</p> <p>4 for purposes of these questions.</p> <p>5 MR. COOK: Would you prefer that we</p> <p>6 publish the -- put on the deposition record the</p> <p>7 entire hundreds of pages of -- of this proposed</p> <p>8 rule?</p> <p>9 MS. BROOKER: I may at trial, so I need</p> <p>10 to interpose my objection here at the deposition.</p> <p>11 MR. COOK: I'm asking whether you're</p> <p>12 going to move to strike his testimony later</p> <p>13 because I didn't give him the entire thing.</p> <p>14 MS. BROOKER: I don't know what I may</p> <p>15 do later, but I'm entitled to interpose</p> <p>16 objections.</p> <p>17 MR. COOK: Okay.</p> <p>18 MS. BROOKER: And that I preserve them</p> <p>19 for a later time. But I have no idea what you're</p> <p>20 going to ask him about it. And I will have no</p> <p>21 idea, since we don't have the entire document</p> <p>22 here, whether a question you put to him may be</p>

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<p>1 Q. And for a brand name drug, would you --</p> <p>2 at the time, did you expect that there would be</p> <p>3 much variation between various purchasers based</p> <p>4 upon volume purchases of the brand name drug?</p> <p>5 A. I believe we had a perception that the</p> <p>6 bigger the purchaser, the larger the discount</p> <p>7 they were likely to be able to achieve; that the</p> <p>8 very largest pharmacy chains, for instance, or</p> <p>9 hospital group purchasing operations, probably</p> <p>10 received the most favorable prices, but that that</p> <p>11 would be -- and that some small independent</p> <p>12 pharmacies might actually pay average wholesale</p> <p>13 price as described in the compendia; that there</p> <p>14 would be a range below that in which most of the</p> <p>15 prices would actually occur.</p> <p>16 Q. Turning to generic drugs for a minute,</p> <p>17 what do you understand to be the differences</p> <p>18 between the market for brand name drugs and the</p> <p>19 market for generic drugs?</p> <p>20 MS. BROOKER: Objection. Form.</p> <p>21 A. If we're going back to 1997 --</p> <p>22 Q. Correct.</p>	<p>1 get much more commoditized in a bag of salt water</p> <p>2 in the drug market?</p> <p>3 A. The only quibble I would provide to</p> <p>4 that question is I never really thought of it as</p> <p>5 classically being part of the pharmaceutical</p> <p>6 market. It was such a -- it was really a</p> <p>7 hospital supply kind of market. It was such a</p> <p>8 standard product that even though it was FDA</p> <p>9 regulated and -- and sterility issues were so</p> <p>10 forth, it tended to be -- hospitals tend to stock</p> <p>11 it, for example, in sterile supplies, put it on</p> <p>12 their cost report as part of sterile supplies</p> <p>13 rather than through their pharmacies.</p> <p>14 Q. But a home infusion provider reimbursed</p> <p>15 under Part B, for example, might be reimbursed</p> <p>16 for sodium saline solution.</p> <p>17 Was that your understanding in '97?</p> <p>18 MS. BROOKER: Objection. Form.</p> <p>19 A. Yes, but whether that was as a supply</p> <p>20 or a drug, I honestly couldn't tell you. I would</p> <p>21 have thought of it as a supply.</p> <p>22 Q. Turning to the market of it, whether we</p>
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<p>1 A. -- I think it's fair to say that I had</p> <p>2 really only a very limited understanding of the</p> <p>3 marketplace for generic drugs and an even more</p> <p>4 limited understanding of the difference between</p> <p>5 the market for generic drugs and for brand drugs.</p> <p>6 And, again, my perception at the time</p> <p>7 was that that was likely more like a commodity</p> <p>8 market in which there was probably more</p> <p>9 purchasing power on the part of the large</p> <p>10 purchasers, but not the same ability to raise</p> <p>11 prices on the up-side to small purchasers that</p> <p>12 prevailed on the brand name side.</p> <p>13 Q. I'd like to focus you just for a</p> <p>14 minute, before we turn to a specific document,</p> <p>15 about a particular generic drug. I think you</p> <p>16 mentioned commodities. Are you familiar with</p> <p>17 sodium saline solution?</p> <p>18 A. Yes.</p> <p>19 Q. It's a bag of salt water, essentially.</p> <p>20 Correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Would you agree with me that you can't</p>	<p>1 call it a drug or -- or a supply, did you have an</p> <p>2 understanding, in 1997, of what the market would</p> <p>3 look like for a product such as sodium saline</p> <p>4 solution?</p> <p>5 MS. BROOKER: Objection. Form.</p> <p>6 MR. BREEN: Objection. Form.</p> <p>7 A. Yes, I did.</p> <p>8 Q. And what was your understanding?</p> <p>9 A. Well, I actually -- in the 1980s, I</p> <p>10 believe, when I was first becoming involved in</p> <p>11 some of these issues in health care economics was</p> <p>12 the first development of hospital group</p> <p>13 purchasing operations, and I recall -- and the</p> <p>14 first widespread circulation of the -- of "Modern</p> <p>15 Healthcare," the magazine, and I recall monthly</p> <p>16 headlines in "Modern Healthcare" about group</p> <p>17 purchasing operations being -- achieving</p> <p>18 discounts of 98 and 99 percent in their purchase</p> <p>19 of basic infusion products and sterile supplies.</p> <p>20 So, my perception was that on the</p> <p>21 supply market, which, again, I understood and</p> <p>22 still would contend is actually a separate market</p>

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<p>1 from the pharmaceutical market that list prices, 2 are essentially entirely meaningless and that 3 only the weakest and smallest scale buyers pay 4 anything close to it. 5 Q. And so, as of 1993, for example, would 6 you be surprised if a single bag of sodium saline 7 solution sold to a provider who bought maybe five 8 would pay \$10 per bag, and a large purchaser who 9 bought a very large volume would pay less than a 10 dollar? 11 MS. BROOKER: Objection. Form. 12 A. I would not have been surprised. 13 Q. Okay. So, to that extent that -- 14 President Clinton referring to a 10-to-1 ratio is 15 something that would be consistent with your 16 understanding of that particular market. 17 Correct? 18 MS. BROOKER: Objection. Form. 19 Q. I'm sorry. You have to verbalize. 20 A. Again, I would have thought that market 21 was a subset of the supplies market rather than 22 the drug market.</p>	<p>1 A. That would be a question I never 2 thought about before today. But today I would 3 say that we always made the distinction between - 4 - between drugs and -- and supplies. And, again, 5 I would fall back on the Medicare green eyeshade 6 distinction between what's sterile supplies and 7 what's pharmacy. 8 MR. COOK: Let's take a break. 9 THE VIDEOGRAPHER: The time is 11:28 10 a.m. We're going off the record, concluding Tape 11 No. 2 in the deposition of Dr. Bruce Vladeck in 12 the matter of In re Pharmaceutical Average 13 Wholesale Price Litigation. 14 (Recess taken.) 15 THE VIDEOGRAPHER: The time is 11:46 16 a.m. We're going back on the record, starting 17 Tape No. 3 of the deposition of Dr. Bruce Vladeck 18 in the matter of In re Pharmaceutical Average 19 Wholesale Price Litigation. 20 Q. Doctor, based upon what we were talking 21 about just before the break, would it be fair to 22 say that while you were administrator of HCFA,</p>
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<p>1 Q. That was my question. But you would 2 have distinguished between the drug market, where 3 10-to-1 would not -- you would not expect to see. 4 Correct? 5 A. That's correct. 6 Q. And the supply market, where sodium 7 saline solution would be found, where there could 8 be a huge variation between a small purchaser 9 purchasing at list price and a very large 10 purchaser purchasing at 99 percent off of list 11 price? 12 MS. BROOKER: Objection. Form. 13 A. I would have made such a distinction, 14 and I would not have been surprised to see those 15 sorts of differentials of the supply market. 16 Q. And in between the commodities supply 17 market of sodium saline and the patent-protected 18 market of a brand name drug, would you expect 19 generic drugs to be somewhere between those two 20 extremes? 21 MS. BROOKER: Objection. Form. 22 MR. BREEN: Objection. Form.</p>	<p>1 you did not understand published average 2 wholesale price to be the average of prices at 3 which wholesalers were selling their drugs to 4 their customers? 5 A. It would -- it would be fair to say 6 that I did not believe it was, in fact, an 7 empirical estimate, that rather it was a -- an 8 amount reported by the manufacturer to -- of the 9 compendium compilers or whatever, yes. 10 Q. And, again, akin to a sticker price? 11 A. That's correct. 12 Q. Where did you get that understanding? 13 A. I believe that was probably what my 14 staff explained to me when I first encountered 15 the concept sometime after I took office. 16 Q. Do you recall anybody within HCFA who 17 was under the belief that average wholesale price 18 was an average of prices at which wholesalers 19 sold drugs to customers? 20 MS. BROOKER: Object to form. And I 21 would just instruct the witness, just, you know, 22 be mindful of not disclosing deliberations,</p>

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<p style="text-align: right;">Page 146</p> <p>1 from the pharmaceutical market that list prices, 2 are essentially entirely meaningless and that 3 only the weakest and smallest scale buyers pay 4 anything close to it. 5 Q. And so, as of 1993, for example, would 6 you be surprised if a single bag of sodium saline 7 solution sold to a provider who bought maybe five 8 would pay \$10 per bag, and a large purchaser who 9 bought a very large volume would pay less than a 10 dollar? 11 MS. BROOKER: Objection. Form. 12 A. I would not have been surprised. 13 Q. Okay. So, to that extent that -- 14 President Clinton referring to a 10-to-1 ratio is 15 something that would be consistent with your 16 understanding of that particular market. 17 Correct? 18 MS. BROOKER: Objection. Form. 19 Q. I'm sorry. You have to verbalize. 20 A. Again, I would have thought that market 21 was a subset of the supplies market rather than 22 the drug market.</p>	<p style="text-align: right;">Page 148</p> <p>1 A. That would be a question I never 2 thought about before today. But today I would 3 say that we always made the distinction between - 4 - between drugs and -- and supplies. And, again, 5 I would fall back on the Medicare green eyeshade 6 distinction between what's sterile supplies and 7 what's pharmacy. 8 MR. COOK: Let's take a break. 9 THE VIDEOGRAPHER: The time is 11:28 10 a.m. We're going off the record, concluding Tape 11 No. 2 in the deposition of Dr. Bruce Vladeck in 12 the matter of In re Pharmaceutical Average 13 Wholesale Price Litigation. 14 (Recess taken.) 15 THE VIDEOGRAPHER: The time is 11:46 16 a.m. We're going back on the record, starting 17 Tape No. 3 of the deposition of Dr. Bruce Vladeck 18 in the matter of In re Pharmaceutical Average 19 Wholesale Price Litigation. 20 Q. Doctor, based upon what we were talking 21 about just before the break, would it be fair to 22 say that while you were administrator of HCFA,</p>
<p style="text-align: right;">Page 147</p> <p>1 Q. That was my question. But you would 2 have distinguished between the drug market, where 3 10-to-1 would not -- you would not expect to see. 4 Correct? 5 A. That's correct. 6 Q. And the supply market, where sodium 7 saline solution would be found, where there could 8 be a huge variation between a small purchaser 9 purchasing at list price and a very large 10 purchaser purchasing at 99 percent off of list 11 price? 12 MS. BROOKER: Objection. Form. 13 A. I would have made such a distinction, 14 and I would not have been surprised to see those 15 sorts of differentials of the supply market. 16 Q. And in between the commodities supply 17 market of sodium saline and the patent-protected 18 market of a brand name drug, would you expect 19 generic drugs to be somewhere between those two 20 extremes? 21 MS. BROOKER: Objection. Form. 22 MR. BREEN: Objection. Form.</p>	<p style="text-align: right;">Page 149</p> <p>1 you did not understand published average 2 wholesale price to be the average of prices at 3 which wholesalers were selling their drugs to 4 their customers? 5 A. It would -- it would be fair to say 6 that I did not believe it was, in fact, an 7 empirical estimate, that rather it was a -- an 8 amount reported by the manufacturer to -- of the 9 compendium compilers or whatever, yes. 10 Q. And, again, akin to a sticker price? 11 A. That's correct. 12 Q. Where did you get that understanding? 13 A. I believe that was probably what my 14 staff explained to me when I first encountered 15 the concept sometime after I took office. 16 Q. Do you recall anybody within HCFA who 17 was under the belief that average wholesale price 18 was an average of prices at which wholesalers 19 sold drugs to customers? 20 MS. BROOKER: Object to form. And I 21 would just instruct the witness, just, you know, 22 be mindful of not disclosing deliberations,</p>

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<p style="text-align: right;">Page 150</p> <p>1 internal deliberations.</p> <p>2 THE WITNESS: Understood.</p> <p>3 A. I -- I think the most accurate way for</p> <p>4 me to answer the question -- I hope his response</p> <p>5 would be to say we did not believe -- I did not</p> <p>6 believe that it was an actually empirically-</p> <p>7 derived number in any form, that it was not</p> <p>8 necessarily, although it was possible, by chance,</p> <p>9 a reflection of what was occurring in the</p> <p>10 marketplace.</p> <p>11 Let me perhaps expand on that. Again,</p> <p>12 the analogy of the sticker price was one that had</p> <p>13 great influence in my thinking, and I would</p> <p>14 probably have expected, at that point, that there</p> <p>15 were always some poor suckers who were paying</p> <p>16 that price, just like there's always folks who</p> <p>17 end up paying list.</p> <p>18 Q. Were you familiar with the distinction</p> <p>19 between average wholesale price as published in</p> <p>20 these compendia, and a list price or direct price</p> <p>21 that manufacturers would -- would have for their</p> <p>22 products?</p>	<p style="text-align: right;">Page 152</p> <p>1 customer?</p> <p>2 MS. BROOKER: Objection. Form.</p> <p>3 MR. BREEN: Objection. Form.</p> <p>4 A. Again, I would have expected there were</p> <p>5 some customers who, in fact, paid the average</p> <p>6 wholesale price, but I didn't not believe that it</p> <p>7 was an accurate reflection of the average revenue</p> <p>8 received by the manufacturer for -- or the</p> <p>9 wholesaler for a particular product.</p> <p>10 Q. I guess to put it another way, you</p> <p>11 understood, between 1993 and 1997, that AWP did</p> <p>12 not represent the average acquisition cost for a</p> <p>13 pharmaceutical?</p> <p>14 A. That's correct. We --</p> <p>15 MS. BROOKER: Objection. Form.</p> <p>16 MR. BREEN: Form.</p> <p>17 A. -- we distinguished acquisition cost</p> <p>18 from average wholesale price, and believed that,</p> <p>19 in general, it was likely to be lower.</p> <p>20 Q. I would like to get back a bit to the -</p> <p>21 - we were talking a bit about the relationship</p> <p>22 between published average wholesale prices and</p>
<p style="text-align: right;">Page 151</p> <p>1 MR. BREEN: Objection. Form.</p> <p>2 MS. BROOKER: Objection. Form.</p> <p>3 A. I would have understood, at the time,</p> <p>4 if someone had made that sort of intellectual</p> <p>5 distinction. I would -- again, trying to</p> <p>6 characterize precisely what I thought ten or 12</p> <p>7 years ago -- I would have been perhaps puzzled or</p> <p>8 surprised, but probably not shocked to learn that</p> <p>9 there was a significant discrepancy between a</p> <p>10 formal published price list and an average</p> <p>11 wholesale price that appeared in a compendium.</p> <p>12 Again, I would have -- let me not put</p> <p>13 so many negatives in there, perhaps for clarity.</p> <p>14 I would have expected that most published price</p> <p>15 lists conformed, by -- that manufacturers</p> <p>16 themselves issued to their salespeople or to</p> <p>17 their customers would have contained list prices</p> <p>18 that were equivalent to the average wholesale</p> <p>19 prices they reported to the compendium.</p> <p>20 Q. Did you understand, between 1993 and</p> <p>21 1997, then that AWP did not refer to the price at</p> <p>22 which a pharmaceutical firm sold a drug to its</p>	<p style="text-align: right;">Page 153</p> <p>1 prices within the marketplace.</p> <p>2 You indicated your belief about the</p> <p>3 relationship between AWP and prices in the</p> <p>4 marketplace for brand name drugs, I think.</p> <p>5 Correct?</p> <p>6 MS. BROOKER: Objection. Form.</p> <p>7 A. I believe I did, yes.</p> <p>8 Q. Okay. And -- and you testified, as I</p> <p>9 recall, that you thought that there was a</p> <p>10 percentage difference, on average, between</p> <p>11 published AWP's and prices within the</p> <p>12 marketplace.</p> <p>13 Do I have that correct?</p> <p>14 MS. BROOKER: Objection. Form.</p> <p>15 A. That is correct.</p> <p>16 Q. Regardless of whether that's what you</p> <p>17 testified before, I've correctly summarized what</p> <p>18 your belief was. Correct?</p> <p>19 A. That's correct.</p> <p>20 Q. When you say that it was an average, do</p> <p>21 I understand correctly it was your belief that it</p> <p>22 wasn't a fixed percentage between the two?</p>

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<p>1 A. That's correct.</p> <p>2 Q. We were talking a little bit earlier</p> <p>3 about the -- the range of prices that a -- a</p> <p>4 commodity, a supply such as sodium chloride</p> <p>5 solution might have, being as much as 100-to-1.</p> <p>6 Correct? You recall that?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. As to generic drugs, would it be</p> <p>9 consistent with your understanding, between 1993</p> <p>10 and 1997, that a generic drug such as vancomycin</p> <p>11 could have a market range of prices as wide as</p> <p>12 that reflected in this chart?</p> <p>13 MS. BROOKER: Objection. Form.</p> <p>14 A. I am -- I think the most accurate way</p> <p>15 to answer that was I am surprised, as of today,</p> <p>16 to see that kind of data, and I think I would</p> <p>17 have been even more surprised, during the '93 to</p> <p>18 '97 period, to see that kind of data.</p> <p>19 Q. But this is data that was reported to</p> <p>20 your agency. Correct?</p> <p>21 A. That's -- that's my understanding, yes.</p> <p>22 Q. And you would have expected members of</p>	<p>1 vancomycin, would you expect your staff to take</p> <p>2 into account the difference between single-source</p> <p>3 drug prices and multiple-source drug prices in --</p> <p>4 in considering changes to Medicare payment</p> <p>5 policies?</p> <p>6 MS. BROOKER: Objection. Form.</p> <p>7 A. The only thing I can observe</p> <p>8 empirically is that I don't recall, in our</p> <p>9 conversations over the years about changing</p> <p>10 Medicare drug pricing policy, the distinction</p> <p>11 between brand and generics arising very often, if</p> <p>12 at all.</p> <p>13 Q. At the time this report was -- was</p> <p>14 written, am I correct that Medicare was</p> <p>15 reimbursing at undiscounted AWP for Part B drugs?</p> <p>16 Correct?</p> <p>17 MS. BROOKER: Objection. Form.</p> <p>18 A. I -- I believe that's correct.</p> <p>19 Q. It was either EAC, according to survey</p> <p>20 --</p> <p>21 A. Right.</p> <p>22 Q. -- or AWP. Right?</p>
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<p>1 your staff to have taken this data into account</p> <p>2 in either a -- and let's start with establishing</p> <p>3 Medicaid or Medicare reimbursement policy.</p> <p>4 MS. BROOKER: Objection. Form.</p> <p>5 A. I would have expected, given the nature</p> <p>6 of this report then, to have been much more</p> <p>7 influenced by the bolded section in the box on</p> <p>8 Page 2.</p> <p>9 Q. And what aspect of that would you</p> <p>10 expect them to be influenced by?</p> <p>11 A. Again, the finding that -- that most</p> <p>12 prices were, in fact, below the AWP, but that in</p> <p>13 two of the cases the differential was 15 to 20</p> <p>14 percent.</p> <p>15 Q. And that would refer, presumably, going</p> <p>16 back to Appendix 2, to the Calcigex and Inferon?</p> <p>17 A. I -- presumably, yes.</p> <p>18 Q. Because those were the single-source</p> <p>19 drugs. Correct?</p> <p>20 A. Yes.</p> <p>21 Q. And to the extent that Medicare</p> <p>22 reimbursed for the multiple-source drug here,</p>	<p>1 A. The only reason I hesitate in response</p> <p>2 to your question is trying to remember whether</p> <p>3 dialysis drugs were treated separately from other</p> <p>4 Part B drugs, but I don't believe they were.</p> <p>5 Q. To the extent that -- that dialysis</p> <p>6 drugs were reimbursed pursuant to 405.517, they</p> <p>7 were being reimbursed by Medicare at 100 percent</p> <p>8 of AWP. Correct?</p> <p>9 A. That is correct.</p> <p>10 Q. And to the extent that the data on the</p> <p>11 chart at Appendix 2 is -- is accurate, that would</p> <p>12 indicate that for Calcigex, for example, if it</p> <p>13 were reimbursed under that methodology, am I</p> <p>14 correct that every single one of the providers</p> <p>15 surveyed would be reimbursed at an amount in</p> <p>16 excess of their acquisition cost? Correct?</p> <p>17 A. That is correct.</p> <p>18 Q. And for Inferon, all but two of the</p> <p>19 providers would have been reimbursed at above</p> <p>20 their acquisition cost. Correct?</p> <p>21 MS. BROOKER: Objection. Form.</p> <p>22 A. That's what it shows, yes.</p>

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<p style="text-align: right;">Page 178</p> <p>1 Q. And for vancomycin, at least one 2 provider would have had a cost of \$3.45 and a 3 reimbursement amount of \$19.17. Correct? 4 A. That's what the charge shows, yes. 5 Q. I'm getting a little bit ahead of 6 myself, but did you ever have discussions within 7 HCFA about whether to change that reimbursement 8 methodology for drugs such as this? 9 MS. BROOKER: I'm going to instruct you 10 to be mindful of not discussing internal pre- 11 decisional deliberations on the record. 12 A. We proposed, a number of times, to 13 change the methodology, and, in fact, the 14 proposal cited by the President, in his speech 15 that we discussed earlier, was one that we had 16 been advocating for -- within the administration 17 since, I believe, about 1995. 18 I think it is fair to say as well that 19 I believed, as -- as far back as '95, that 85 20 percent of average wholesale price as a payment 21 method was inferior to something closer than 22 average acquisition cost, but that the</p>	<p style="text-align: right;">Page 180</p> <p>1 that the Office of Management and Budget, and 2 perhaps the Department of Health and Human 3 Services themselves, would not authorize us to 4 undertake the data collection to determine 5 acquisition costs, and that we -- our perception 6 was we did not believe we had the authority to go 7 to a percentage of AWP as an alternative 8 methodology without legislation. 9 Q. Well, the -- the regulation that was 10 promulgated in 1991 providing for estimated 11 acquisition cost according to a survey or average 12 wholesale price as published in the Red Book, was 13 promulgated by the Department of Health and Human 14 Services. Correct? 15 A. That is correct. 16 Q. And an alternative regulation changing 17 that rule also could have been promulgated by the 18 Department of Health and Human Services any time 19 prior to the enactment of the Balanced Budget Act 20 of 1997. Correct? 21 MS. BROOKER: Objection. Form. 22 A. I -- I'd have to check, but it was my</p>
<p style="text-align: right;">Page 179</p> <p>1 administrative difficulties, and the potential 2 administrative burden on physicians as a 3 political issue, if not a real issue, made it 4 likelier that we would be able to succeed with 5 the legislative proposal still tied to AWP than 6 one that went all the way back to its acquisition 7 costs. 8 Q. Now, as I understand it, from '91 -- 9 strike that. 10 As I understand it, during the time you 11 were a HCFA administrator, from 1993 until 1997, 12 reimbursement for Part B drugs under Medicare, 13 under the regulation 405.517, was made pursuant 14 to HHS regulation. Correct? 15 A. That is correct. 16 Q. And that could have been changed 17 without legislation. Correct? 18 MS. BROOKER: Objection. Form. 19 A. Theoretically, yes. We were -- it was 20 my perception, during that period, that the 21 statute -- the statute offered us the alternative 22 of an acquisition price-based methodology, but</p>	<p style="text-align: right;">Page 181</p> <p>1 perception at the time that our legal authority 2 pretty much left us with those -- in the absence 3 of further legislation, pretty much left us with 4 those two alternatives; in other words, 100 5 percent of AWP or actual acquisition price. 6 My -- I don't recall whether that was 7 because of a perception that Congress would 8 object to any effort to use a fraction of AWP or 9 -- I don't -- the opinion that we had only those 10 two alternative -- let me restate that. 11 It was my belief, at the time, that the 12 -- having only those two alternatives was an 13 unavoidable reality. Whether that was legal or 14 political, I'm not sure I was clear at the time, 15 and I'm certainly not clear now. 16 Q. So, as I understand it, between 1993 17 and 1997, according to regulation, HCFA could 18 reimburse based upon two methodologies. 19 Correct? 20 A. That's correct. 21 Q. One was the published average wholesale 22 price. Correct?</p>

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<p>1 A. That's correct.</p> <p>2 Q. One was EAC, established according to</p> <p>3 survey. Correct?</p> <p>4 A. That's correct.</p> <p>5 Q. We'll get to it later, but for whatever</p> <p>6 reason, that was not available to you because the</p> <p>7 surveys were not or could not be conducted?</p> <p>8 A. That's correct.</p> <p>9 MS. BROOKER: Objection to form.</p> <p>10 Q. And so, your understanding was that</p> <p>11 pursuant to regulation, your only alternative</p> <p>12 between '93 and '97, while you were administrator</p> <p>13 of HCFA, was to pay based upon the published</p> <p>14 average wholesale price. Correct?</p> <p>15 A. That's correct.</p> <p>16 Q. And during the time that you were</p> <p>17 paying the published average wholesale price, you</p> <p>18 were aware that average wholesale price exceeded</p> <p>19 acquisition cost. Correct?</p> <p>20 MS. BROOKER: Objection. Form.</p> <p>21 A. Yes.</p> <p>22 Q. You were aware that for generic drugs,</p>	<p>1 administrator of HCFA, considered alternatives to</p> <p>2 100 percent of AWP. Correct?</p> <p>3 You, as administrator of HCFA,</p> <p>4 considered alternatives to reimbursing at 100</p> <p>5 percent of AWP. Correct?</p> <p>6 A. I don't know if we're getting into</p> <p>7 deliberative --</p> <p>8 MS. BROOKER: You should be mindful</p> <p>9 that you should not disclose any pre-decisional</p> <p>10 deliberative process.</p> <p>11 MR. COOK: I think it's going to be</p> <p>12 easier if you either direct him not to answer or</p> <p>13 let him answer, because I'm aware -- I'm a little</p> <p>14 leery of having the witness put in the difficult</p> <p>15 position of having to parse within his head --</p> <p>16 A. Well, let me -- I can say I was aware</p> <p>17 that conceptually there were alternatives to 100</p> <p>18 percent of AWP.</p> <p>19 MS. BROOKER: Let me say you can state</p> <p>20 what your understanding was in your official</p> <p>21 capacity, and you can certainly state what the</p> <p>22 official policy was or the regulation, or what</p>
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<p>1 the difference could be greater than for brand</p> <p>2 name drugs. Correct?</p> <p>3 MR. BREEN: Objection.</p> <p>4 A. I'm not certain I was aware of that.</p> <p>5 Q. But for supplies such as sodium</p> <p>6 chloride, you were aware that the difference</p> <p>7 could be as much as 99 percent. Correct?</p> <p>8 A. Yes, I was.</p> <p>9 MR. BREEN: Objection. Form.</p> <p>10 MS. BROOKER: Objection. Form.</p> <p>11 Q. And the same would be true for other</p> <p>12 commodity products similar to sodium chloride</p> <p>13 such as, for example, dextrose in water.</p> <p>14 Correct?</p> <p>15 MR. BREEN: Objection. Form.</p> <p>16 A. Yes, that's correct. Or sterile saline</p> <p>17 or something of that sort.</p> <p>18 Q. Which are two of the other drugs at</p> <p>19 issue in this case. Correct?</p> <p>20 A. I wasn't aware that -- that they were,</p> <p>21 but okay.</p> <p>22 Q. And during that time, you, as</p>	<p>1 the statute was. You just cannot discuss pre-</p> <p>2 decisional deliberative conversations that you --</p> <p>3 that you had with others.</p> <p>4 THE WITNESS: I think I got that.</p> <p>5 Q. All right. Without revealing what the</p> <p>6 deliberations were, were there deliberations</p> <p>7 within HCFA about alternative methods for</p> <p>8 reimbursing to undiscounted AWP?</p> <p>9 MS. BROOKER: Objection to form.</p> <p>10 A. Extensive discussion.</p> <p>11 Q. Who -- who was involved in those</p> <p>12 extensive discussions?</p> <p>13 A. I don't know if that gets too</p> <p>14 deliberative.</p> <p>15 MS. BROOKER: You can say who was</p> <p>16 involved in deliberations.</p> <p>17 A. I would say that with the exception of</p> <p>18 the Medicaid folks, the list of people I</p> <p>19 enumerated earlier as experts I would have</p> <p>20 consulted on these issues would have been</p> <p>21 involved, whoever the deputy administrator was at</p> <p>22 the time would have been involved. And, again,</p>

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1 probably other members of the staff of the office
2 administrator probably would have been involved,
3 as would additional staff in the Office of
4 Legislation and Policy, in addition to the
5 individuals I named earlier.

6 Q. And it involved numerous meetings at
7 which the -- the -- the possibilities were
8 discussed; I take it?

9 MS. BROOKER: Objection. Form.

10 A. I would say we were, in 1996 and 1997 -
11 - certainly probably beginning in 1995, there
12 were very frequent conversations about budgetary
13 issues and policies with potential budgetary
14 impacts of one kind or another, and there was
15 always a list of potential policies and changes
16 to Part B drug reimbursement was frequently on
17 those lists, and was not discussed at every
18 meeting, but was frequently discussed.

19 Q. How many alternatives were discussed?

20 MS. BROOKER: Objection. You should
21 not discuss exactly what -- you should not
22 discuss any of your deliberations, so you

1 And I also object that these questions
2 are incredibly vague. So, I object to form. I
3 don't know exactly what program we're even
4 talking about. I don't know what time period
5 we're talking about. I don't know what the
6 specifics are that you're talking about in this
7 whole line of questions.

8 MR. COOK: But you understand enough
9 that you won't let him answer it?

10 MS. BROOKER: If he's going to talk
11 about internal deliberations. And -- and, again,
12 just for the record, it's not that I won't let
13 him talk about it. I am here to protect on --
14 not on behalf of the witness, but on behalf of
15 the government, deliberative process privilege.
16 It's not my privilege. It's not the witness'
17 privilege. It's the federal government's
18 privilege.

19 MR. COOK: All right. The United
20 States, who has sued my client, will not allow
21 the witness to talk about it.

22 Is that fair to say?

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1 shouldn't talk about -- I mean, that's -- that's
2 prohibited.

3 MR. COOK: Well, are you instructing
4 him not to answer?

5 MS. BROOKER: You can talk about what
6 official policy was.

7 MR. COOK: All right. I'll make it
8 easy.

9 Q. In your internal deliberations at HCFA,
10 how many alternative methods of reimbursement did
11 you consider?

12 A. I couldn't say. I -- it's not a
13 question of privilege. I couldn't say.

14 Q. Okay. But within your internal
15 deliberations, you did consider alternative
16 methods of reimbursement. Correct?

17 A. That is correct.

18 Q. And, again, to -- to make the record as
19 sharp as possible, what did you discuss in those
20 deliberations?

21 MS. BROOKER: Objection. You cannot
22 discuss exactly what your deliberations were.

1 MS. BROOKER: I don't think that's a
2 fair characterization.

3 MR. COOK: Okay.

4 MS. BROOKER: Look, Chris --

5 MR. COOK: I know. I know.

6 MS. BROOKER: We have this issue before
7 the Judge. There's no reason to bicker about it
8 before the witness. Let's just all be
9 professional about it.

10 Q. And so, it is fair to say that during
11 the time you were the administrator of HCFA, the
12 agency did not choose to change the manner in
13 which it reimbursed Medicare Part B drugs?

14 MS. BROOKER: Objection. Form.

15 A. I would -- I would frankly personally
16 object to that characterization because I had a
17 growing feeling -- again, I would put this in a
18 period probably beginning about 1995 through the
19 time I left the government -- of frustration that
20 we were significantly overpaying for Part B
21 drugs, and that because of some combination,
22 frankly, of political and legal constraints, we

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<p>1 were unable to change it.</p> <p>2 Again, whether that was a matter of law</p> <p>3 or a matter of political judgment, whether I was</p> <p>4 clear then, I'm not clear now, but it was</p> <p>5 certainly a source of very great frustration to</p> <p>6 me that we continued to pay what I believed was</p> <p>7 excessive amounts for the drugs.</p> <p>8 Q. And so, "choose" was a bad choice of</p> <p>9 words?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Did not, in fact, change the way</p> <p>12 in which it reimbursed it, for several reasons?</p> <p>13 MS. BROOKER: Objection. Form.</p> <p>14 A. Those methods were not, in fact,</p> <p>15 changed until 2004, I believe.</p> <p>16 Q. You indicated that political</p> <p>17 considerations were one of the bases -- let me</p> <p>18 rephrase that.</p> <p>19 You indicated the political pressures</p> <p>20 were one of the reasons why the methodology was</p> <p>21 not changed. Correct?</p> <p>22 A. I did, yes. That's correct.</p>	<p>1 negatives in it. I'm not even going to try to</p> <p>2 clean that one up. I apologize.</p> <p>3 You had communications with Congress</p> <p>4 during this time period about the issue of</p> <p>5 Medicare Part B reimbursement for prescription</p> <p>6 drugs?</p> <p>7 A. I don't know the extent to which I did</p> <p>8 personally, but certainly at the staff level</p> <p>9 there was continual conversation about this</p> <p>10 issue.</p> <p>11 Q. Do you know the extent to which the</p> <p>12 facts underlying these policy decisions were</p> <p>13 communicated by your staff to Congress?</p> <p>14 MS. BROOKER: Objection. Form.</p> <p>15 A. I don't know the extent to which I am a</p> <p>16 reliable source of information in this regard,</p> <p>17 but it is my perception, again, that the general</p> <p>18 sense of a 15, 20 percent spread between average</p> <p>19 wholesale price and actual acquisition or actual</p> <p>20 market cost was very widespread within the policy</p> <p>21 community in Washington, so that the</p> <p>22 Congressional staff and the HCFA staff and other</p>
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<p>1 Q. And it's possible that legislative</p> <p>2 impediments were one of the reasons why the</p> <p>3 methodology was not changed. Correct?</p> <p>4 MS. BROOKER: Objection. Form.</p> <p>5 A. Again, I would -- I would restate it.</p> <p>6 What I was trying to say was that we believed</p> <p>7 that -- there's sort of two parts to this -- that</p> <p>8 any effort to change it through any mechanism</p> <p>9 would create political objections and might well</p> <p>10 prevent us from moving forward. Some of those</p> <p>11 barriers might have been legislative, but whether</p> <p>12 we actually required legislation to make changes,</p> <p>13 again, is something I'm a little bit unclear</p> <p>14 about.</p> <p>15 Q. It is fair to say that one of -- it was</p> <p>16 not a reason for the lack of a change in</p> <p>17 methodology that you were relying upon average</p> <p>18 wholesale price to represent an average of</p> <p>19 acquisition prices?</p> <p>20 MS. BROOKER: Objection. Form.</p> <p>21 A. Please restate that.</p> <p>22 Q. You're right. That has way too many</p>	<p>1 HHF staff and, frankly, industry representatives,</p> <p>2 would have all seen the same documents, would all</p> <p>3 have shared the same sort of gossip and</p> <p>4 perceptions.</p> <p>5 In addition to which certainly at the</p> <p>6 time of the President's speech, I'm almost</p> <p>7 certain in 1996, and it's possible in 1995 there</p> <p>8 were official savings estimates from OMB and the</p> <p>9 Congressional budget office of what an adoption</p> <p>10 of, say, a proposal to go to 85 percent of AWP</p> <p>11 would save the Medicare program.</p> <p>12 So, there were numbers, quantitative</p> <p>13 estimates, of the effect of this change that were</p> <p>14 blessed by the official numbers blessers, so</p> <p>15 there was sort of a common set of parlance</p> <p>16 expectation and understanding about the magnitude</p> <p>17 of these issues.</p> <p>18 Q. And from -- you mentioned political</p> <p>19 pressures that -- that prevented changes, and a</p> <p>20 change to methodology.</p> <p>21 From where did those political</p> <p>22 pressures come, in your experience?</p>

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<p>1 MS. BROOKER: Objection. Form.</p> <p>2 A. It could very well have. Again, as</p> <p>3 I believe I testified at our last session, it was</p> <p>4 not one of the major sort of issues on my</p> <p>5 attention or on which I was focusing, but to the</p> <p>6 extent that it came up it was as likely to come up</p> <p>7 through an e-mail exchange as through an oral</p> <p>8 conversation or a written document.</p> <p>9 Q. And at least for me personally, if</p> <p>10 I wanted to go back and recreate what I was doing,</p> <p>11 and the various issues were that were raised</p> <p>12 during a particular time period, looking at my old</p> <p>13 e-mails is -- is the most effective way for me to</p> <p>14 do that nowadays.</p> <p>15 Would that be true for you as well</p> <p>16 during this time period?</p> <p>17 MS. BROOKER: Objection. Form.</p> <p>18 A. I don't know that I ever had the</p> <p>19 opportunity to do that or think about it. It</p> <p>20 would certainly be a very useful spur to the</p> <p>21 memory. I would probably get so bogged down in</p> <p>22 being reminded of things I had totally forgotten</p>	<p>1 A. Oh, I wouldn't be able to say. I</p> <p>2 would guess he was roughly a contemporary of mine,</p> <p>3 and I would have been in my mid 40s.</p> <p>4 Q. Do you recall any conversations</p> <p>5 with Randall Graydon relating specifically to</p> <p>6 average wholesale price and -- and those drug</p> <p>7 reimbursement issues?</p> <p>8 MS. BROOKER: Objection. Form.</p> <p>9 A. The only conversation I recall with</p> <p>10 -- specific conversation I recall with a member of</p> <p>11 my staff about average wholesale price and drug</p> <p>12 pricing issues, which I believe we discussed last</p> <p>13 time, although I'm not certain, was with Tom</p> <p>14 Hoyer, relative to the Medicare drug pricing</p> <p>15 issues, and -- and the issue of average wholesale</p> <p>16 price.</p> <p>17 I also know that I had one or more</p> <p>18 conversations with his supervisor, Mr. Ault, at</p> <p>19 some point. Whether it was the same conversation</p> <p>20 or a separate conversation, I couldn't say.</p> <p>21 Q. Do you recall when those</p> <p>22 conversations or conversation took place?</p>
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<p>1 that it might not be that efficient, but it would</p> <p>2 -- I think it would be very helpful to try to</p> <p>3 reconstruct.</p> <p>4 Q. You mentioned the name of Randall</p> <p>5 Graydon as your preeminent drug reimbursement</p> <p>6 expert when you were there.</p> <p>7 Can you tell me a little bit --</p> <p>8 what's Randall Graydon's background?</p> <p>9 A. I honestly don't know. He was</p> <p>10 already -- I'm trying to remember if he actually</p> <p>11 had formal training in pharmacy. I believe he</p> <p>12 did. He may have, but I do not recall. He may</p> <p>13 have actually had been licensed as a professional</p> <p>14 pharmacist before, or at about the time he came to</p> <p>15 work at the agency.</p> <p>16 He certainly had been working on</p> <p>17 drug issues for the organization for a number of</p> <p>18 years before I got there. I think it's been a</p> <p>19 good part of his professional career at the</p> <p>20 agency.</p> <p>21 Q. How old was he at the time you were</p> <p>22 administrator?</p>	<p>1 A. I couldn't tell you when -- it was</p> <p>2 early -- I recall the conversation with Mr. Hoyer</p> <p>3 particularly because it was really, I think, the</p> <p>4 first time I ever got -- had any extensive</p> <p>5 substantive conversation about the issue of</p> <p>6 average wholesale price, and learned a little bit</p> <p>7 about the history of the implementation of the</p> <p>8 Medicare provisions for OBRA '90 relative to the</p> <p>9 efforts to survey physicians about acquisition</p> <p>10 cost that was aborted, and so forth.</p> <p>11 And I just, for some reason,</p> <p>12 remember his referring to the Red Book and</p> <p>13 explaining to me that it was derived not from</p> <p>14 independent investigation but from information</p> <p>15 supplied to the publisher by the manufacturers.</p> <p>16 Q. Do you remember anything else that</p> <p>17 Mr. Hoyer or Mr. Ault told you relating to average</p> <p>18 wholesale price?</p> <p>19 MS. BROOKER: Objection. Calls for</p> <p>20 hearsay. Also, I just want to be mindful just to</p> <p>21 instruct the witness to be careful about</p> <p>22 disclosing pre-decisional deliberative</p>

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<p>1 conversations.</p> <p>2 A. I do believe there was some</p> <p>3 discussion of the extent to which average</p> <p>4 wholesale price was an artificial construct of</p> <p>5 some sort, rather than a -- a true empirical</p> <p>6 reflection of actual prices in market</p> <p>7 transactions.</p> <p>8 Q. Do you recall if anybody else was</p> <p>9 part of this conversation?</p> <p>10 A. I don't. It could have been, but I</p> <p>11 -- I don't recall.</p> <p>12 Q. Do you remember any other details</p> <p>13 about the conversation?</p> <p>14 MS. BROOKER: Objection.</p> <p>15 MR. COOK: What's the objection?</p> <p>16 MS. BROOKER: It calls for hearsay.</p> <p>17 I'm entitled to put that objection on the record.</p> <p>18 MR. COOK: You're objecting to</p> <p>19 hearsay at a deposition?</p> <p>20 MS. BROOKER: I have to make my</p> <p>21 objections at the deposition. Absolutely.</p> <p>22 MR. COOK: I think we can -- I</p>	<p>1 record, that when I say "objection, form," that</p> <p>2 also covers hearsay objections, then I can agree</p> <p>3 to that.</p> <p>4 MR. COOK: I'm not agreeing that</p> <p>5 objections to form includes hearsay. Fine. Make</p> <p>6 whatever objections you want.</p> <p>7 MS. BROOKER: Well, if you would</p> <p>8 like that agreement, then I don't have to say</p> <p>9 "hearsay." I will just say "objection, form."</p> <p>10 MR. COOK: Make whatever objections</p> <p>11 you want.</p> <p>12 MR. BREEN: See, the problem -- the</p> <p>13 problem, Chris -- and I -- I realize you're</p> <p>14 irritated by this. Okay?</p> <p>15 The problem is we've got this thing</p> <p>16 cross-noticed so many doggone ways, and there's so</p> <p>17 many rules, there's always one place where you</p> <p>18 need to make your hearsay objections, and this is</p> <p>19 arguable on the record.</p> <p>20 So, if everybody could agree that</p> <p>21 form objections includes hearsay, and they're all</p> <p>22 our respected rules, it would certainly resolve</p>
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<p>1 think we can all agree that hearsay objections are</p> <p>2 preserved until trial.</p> <p>3 MS. BROOKER: I'm going to make my</p> <p>4 objections when appropriate.</p> <p>5 MR. COOK: You're coaching the</p> <p>6 witness.</p> <p>7 MS. BROOKER: It's not coaching the</p> <p>8 witness.</p> <p>9 MR. COOK: Come on.</p> <p>10 Q. Do you remember anything else about</p> <p>11 the conversation?</p> <p>12 MS. BROOKER: Okay. Let me --</p> <p>13 Chris --</p> <p>14 MR. COOK: First of all, it's not</p> <p>15 hearsay to ask him if he remembers any of the</p> <p>16 details about the conversation.</p> <p>17 MS. BROOKER: I have allowed you to</p> <p>18 ask him many questions about who was present at</p> <p>19 conversations and so forth. And I haven't made</p> <p>20 hearsay objections. Only when I hear that it</p> <p>21 calls for hearsay.</p> <p>22 If you want to agree, on the</p>	<p>1 your issue about potential -- about this -- this -</p> <p>2 - this -- this coaching suspicion you've got.</p> <p>3 MR. COOK: The deal, Jay, is</p> <p>4 litigating only in federal court.</p> <p>5 MR. BREEN: Well --</p> <p>6 MR. COOK: And I don't think that</p> <p>7 there's --</p> <p>8 MR. BREEN: One objection -- do you</p> <p>9 want to --</p> <p>10 MR. COOK: Does anybody think that</p> <p>11 hearsay objections have to be made at a -- at a</p> <p>12 deposition --</p> <p>13 MR. BREEN: Where's John McDonald?</p> <p>14 MR. COOK: -- under the federal</p> <p>15 rules?</p> <p>16 MR. MCDONALD: I'm right here.</p> <p>17 MR. BREEN: This isn't only under</p> <p>18 the federal -- I don't know about -- I don't know</p> <p>19 about that. Is -- are we -- are we going to agree</p> <p>20 that in any -- are we agreeing in any state case -</p> <p>21 - there's some folks in state cases here -- that</p> <p>22 the federal rules totally apply to this thing?</p>

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<p>1 you testified about, back on May 4th relating to 2 going to an actual acquisition cost methodology 3 for payment of drugs? 4 MS. BROOKER: Objection. Form. 5 A. That is my -- consistent with my 6 memory of what we had proposed, yes. 7 Q. And could you describe what the 8 payment methodology would have been if this 9 statutory proposal had been adopted by Congress? 10 A. Well, again, it would have been 11 lower of average wholesale price, now with -- with 12 the little clause there under Section B, the 13 opportunity to write regulations -- defining what 14 average wholesale price was or actual acquisition 15 cost, with a further provision that if there was 16 insufficient information about the actual 17 acquisition cost to the individual physician or 18 supplier, we could employ national average data. 19 Q. Assuming that this is language from 20 a budget proposal for the administration in Fiscal 21 Year 1998, who would have actually drafted this 22 language?</p>	<p>1 Care an explicit dispensing fee. 2 Correct? 3 A. That's how I understand it, yes. 4 Q. Was there any discussion within 5 HCFA that the creation of that dispensing fee was 6 to make up, in some measure, for the lost profits 7 from going from AWP to acquisition costs? 8 MS. BROOKER: Objection. 9 I would just instruct you to be 10 mindful of not disclosing pre-decisional 11 deliberations, and to just stick to policy. 12 A. I don't know if this addresses the 13 objection of the concern or not. I don't recall 14 any specific discussion about that. My 15 presumption was that as a policy it would have the 16 effect similar to what you described, but I don't 17 have any specific memory of this provision at all, 18 frankly. 19 Q. Okay. Who would be the best person 20 to ask within HCFA for the -- the reason that this 21 dispensing fee for pharmacies provision was 22 included in the proposed legislation?</p>
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<p>1 A. Probably the actual -- the actual 2 drafting of the language would have been done, I 3 believe, by staff in the counsel's office at HHS, 4 working with HCFA staff and staff of the Office of 5 Legislation. 6 Q. Do you recall being involved in the 7 crafting of -- of the language relating to this 8 budget proposal? 9 A. I -- I don't believe I was involved 10 in the actual language drafting, no. 11 Q. If you look at the -- Page 4 of the 12 facsimile, which is Page 0322 on the Bates 13 numbers, the second paragraph -- the first full 14 paragraph at the top refers to a dispensing fee 15 for pharmacies. 16 Absent this legislation, or at the 17 time this legislation was proposed, Medicare did 18 not pay a dispensing fee for pharmacies for drugs 19 reimbursed under Part B. Is that correct? 20 A. That is correct. 21 Q. And this would have given the 22 Secretary authority to pay entities such as Ven-A-</p>	<p>1 A. I think probably again Ms. Buto or 2 Mr. Hoyer. 3 Q. The other provision that piques my 4 interest -- and unfortunately it's cut off -- is 5 the Section 11237 immediately following. This 6 says: 7 "Payments to physicians' 8 assistants, nurse practitioners, and clinical 9 nurse specialists." 10 And the first subheading refers to: 11 "Coverage in home and ambulatory 12 settings in which a facility or a provider fee is 13 not billed for physicians' assistants, nurse 14 practitioners, and clinical nurse specialists." 15 First, do you know what that teaser 16 of a heading relates to in terms of the proposed 17 legislation? 18 MS. BROOKER: Objection. Form. 19 A. I have a surmise. I don't have any 20 direct memory. 21 Q. And what would the surmise be? 22 A. My guess would be it would permit</p>

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<p>1 of -- of this document. 2 MS. BROOKER: What's the Bates 3 number on it? 4 MR. COOK: It's Bates Page 0251. 5 Q. And if you count up from the 6 bottom, it's the sixth paragraph up from the 7 bottom. 8 A. Beginning "among doctors"? 9 Q. Beginning with "armed with this 10 kind of evidence." It's on Page 251, at the 11 bottom. 12 A. Oh, 251. 13 Q. Yes. 14 A. I'm sorry. Yes, I see it. Thank 15 you. 16 Q. First of all, do you remember this 17 -- this article and -- and being interviewed for 18 this article, Dr. Vladeck? 19 A. No, I do not. 20 Q. Let me read to you a couple of 21 quotes that are attributed to you, and -- and you 22 can tell me, and I'll ask you a couple of</p>	<p>1 Q. You say that they were concerned 2 that the docs would get very mad and that there 3 would be a political problem. 4 What was the political problem to 5 which you were referring? 6 MR. BREEN: Objection. Form. 7 A. That particularly given the 8 partisan composition and proclivities of -- of the 9 Congress, there would be all sorts of 10 denunciations to the administration. There would 11 probably be hearings. There would be allegations 12 of all sorts ginned up by the campaign. 13 Q. And the result of that was that 14 HCFA continued to pay based upon average wholesale 15 price. Correct? 16 MS. BROOKER: Objection. Form. 17 A. That is correct. 18 Q. And then in the next paragraph 19 there is a quote attributed to a HCFA 20 spokesperson. And I'll just read the quote: 21 "It's very clear, given the way we 22 reimburse physicians, that we're overpaying."</p>
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<p>1 questions about it. The lead-in paragraph to your 2 quote is: 3 "Armed with this kind of evidence, 4 the Clinton Administration tried to tamp down drug 5 costs by proposing a rule of limited 6 reimbursements to what doctors actually paid for 7 their drugs. The rule went nowhere, a casualty, 8 according to a former HCFA head, Vladeck, of 9 timidity of the agency's Office of the Department 10 of Health and Human Services." 11 And then the quote attributed to 12 you in the next paragraph is: 13 "Some of my colleagues in HHS were 14 concerned that the docs would get very mad, that 15 there would be a political problem, and it would 16 be burdensome, Vladeck recalled, if we (HCFA 17 officials) weren't permitted to go ahead with it." 18 First of all, do you remember 19 giving that quote to the Tribune? 20 A. Not specifically, although I -- I 21 would not question its accuracy or doubt that I 22 did, in fact, say that.</p>	<p>1 MS. BROOKER: I'm sorry, Chris. I 2 didn't mean to interrupt you, but where are you? 3 Oh, I see. I'm there. 4 MR. COOK: It's the second half of 5 the next paragraph. 6 MS. BROOKER: Okay. 7 Q. It's -- I think a HCFA spokesperson 8 gave the following quote, according to the 9 article, to the Chicago Tribune. 10 "It's very clear, given the way we 11 reimburse physicians, that we're overpaying. The 12 law requires us to overpay. There's no 13 flexibility. That's why we asked to have it 14 reduced." 15 Is that a fair statement of -- of 16 HCFA's position at the time, Dr. Vladeck? 17 A. Yes. 18 Q. And HCFA was overpaying because of 19 political considerations that prevented it from 20 changing the law? 21 MR. BREEN: Objection. Form. 22 MS. BROOKER: Objection. Form.</p>

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<p>1 A. I would distinguish two processes. 2 There are political considerations that, in 3 addition to legal considerations, prevented us 4 from seeking to change the policy 5 administratively. And then there was political 6 opposition to -- efforts to change the law itself. 7 Q. And so, it wasn't -- what I'm 8 trying to get at is HCFA wasn't overpaying because 9 it was fooled into believing that what it was 10 paying was actual acquisition costs. 11 Correct? 12 MS. LIANG: Object to the form. 13 MR. BREEN: Objection. Form. 14 MS. BROOKER: Objection. Form. 15 A. We did not believe we were paying 16 actual acquisition costs. 17 MR. COOK: Let's take a short 18 break. 19 THE VIDEOGRAPHER: The time is 20 10:47 a.m. We're going off the record, concluding 21 Tape No. 7. 22 (Recess taken.)</p>	<p>1 acquisition cost, and the estimated acquisition 2 cost would be determined based upon a survey of 3 the actual invoice prices paid for the drug? 4 Is that correct? 5 A. That's correct. 6 Q. And that in estimating the 7 acquisition cost, the agency or the agency's 8 carriers, at least, would be allowed to include 9 such factors as inventory waste and spoilage. 10 Right? 11 A. That's correct. 12 Q. As I understand it, HCFA never 13 undertook the surveys authorized by Section 14 405.517. Right? 15 A. Not to get into semantics, the 16 surveys were never, in fact, conducted, I believe. 17 Q. Who was responsible for -- well, 18 let me strike that. 19 Did HCFA take any steps towards 20 conducting such surveys? 21 A. My understanding, which, frankly, I 22 think is based on information that's become</p>
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<p>1 THE VIDEOGRAPHER: The time is 2 11:01 a.m. We're going back on the record, 3 starting Tape No. 8. 4 Q. Dr. Vladeck, I'd like to ask you 5 just a few questions about the attempted survey 6 that HCFA undertook pursuant to 42 CFR 405.517, as 7 it was promulgated in November of 1991. 8 I've asked you to turn to Exhibit 9 Abbott 038 in the exhibit books before you. 10 MR. COOK: And for the record, 11 Exhibit Abbott 038 is a copy of that regulation 12 from 1991 before it was amended several years 13 later. 14 Q. And if you could look to Paragraph 15 B, which describes the methodology. Do you see 16 that? 17 A. Yes, sir. 18 Q. And am I correct that Paragraph B 19 describes the methodology under which HCFA would 20 pay for drugs under Part B -- as Part B of 21 Medicare -- at the lower of either the national 22 average wholesale price or the estimated</p>	<p>1 available to me in the course of either my 2 preparation for this deposition or my earlier 3 involvement with Mr. Azorsky on the other 4 litigation, is that HCFA actually was prepared to 5 direct its carriers to undertake this survey, and 6 then the process was stopped -- I believe I have 7 been told, or I read somewhere that that was 8 because the Office of Management and Budget 9 refused to approve the survey instrument itself. 10 Q. Do you know why it was the Office 11 of Management and Budget refused to approve the 12 survey? 13 MS. BROOKER: Objection. Form. 14 A. I don't know why. I am -- I am 15 aware that in that time period the Office of 16 Management and Budget was very sensitive to 17 concerns about allegations about the burden that 18 government surveys in general were imposing on the 19 private sector that was, in part, the rationale 20 for why OMB had to approve all surveys. 21 And it is my understanding, again, 22 secondhand or thirdhand, that there was</p>

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<p>1 should have known earlier; that, in fact, the 15 2 to 25 percent or 15 to 20 percent was the rule of 3 thumb for sole-source brand drugs, that, in fact, 4 the expectation, the belief about generics, was 5 that it was more likely to be between 25 and 40 6 percent difference between actual market price and 7 average wholesale price. 8 Q. So, when you testified about your 9 belief that the difference was somewhere between 10 15 and 20 percent, you were just talking about 11 your own personal belief and not the belief of 12 others at HCFA. Is that correct? 13 MS. BROOKER: Objection to form. 14 A. I think it's fair to say that my 15 own beliefs were formed on the basis of what I was 16 told by my colleagues at HCFA. So, I think if I 17 described that as the consensus view among the 18 people I would have consulted or would have 19 advised me about the issue, that would be a fair 20 characterization, because there's nowhere else 21 from which I would have got that impression. 22 Q. Did you have discussions with</p>	<p>1 a somewhat sore subject. I don't know that there 2 was anyone in the agency who had specific 3 responsibility for detailed knowledge of the 4 prescription drug marketplace. 5 Q. I take it some of them did have 6 knowledge of the prescription drug marketplace. 7 Is that correct? 8 MS. CONNOLLY: Objection to form. 9 A. That was my perception. 10 Q. Let's take a look once again at the 11 1991 regulation. I believe it's been marked as 12 Exhibit Abbott 261? 13 A. Yes, sir. 14 Q. And I believe you may have 15 testified earlier that you had seen this 16 regulation before. Is that correct? 17 A. That is correct. 18 Q. What I want you to do is look at 19 the page with the No. 62 in the upper right-hand 20 corner. 21 A. Yes, sir. 22 Q. Under the "comment" section it --</p>
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<p>1 others at HCFA prior to 1996 or 1997 concerning 2 what the difference between AWP and transaction 3 prices was for generics? 4 MS. BROOKER: Objection. 5 I would ask you also to be mindful 6 of not discussing predecisional deliberative 7 conversations. 8 A. I think I can say that, again, in 9 thinking about the average wholesale price and its 10 relationship to anything else, it was not prior to 11 then that I distinguished between generics and 12 brand name drugs and, therefore, it's unlikely I 13 would have had such a conversation at all. 14 Q. Okay. How many people worked at 15 HCFA during the time that you were there? 16 MS. BROOKER: Objection. 17 A. About 4,000. 18 Q. And did some of those people have 19 the responsibility to understand what was going on 20 in the marketplace? 21 MS. BROOKER: Objection. 22 A. That's an interesting question and</p>	<p>1 it talks about the reimbursement level for drugs 2 and it says: 3 "We received a great many comments 4 on this issue, primarily from oncologists, 5 indicating that our 85 percent standard was 6 inappropriate." 7 Was it your understanding that 8 originally HCFA proposed that the reimbursement 9 level be set at 85 percent of AWP? 10 MS. BROOKER: Objection. 11 A. Yes. 12 Q. And it published a proposed reg and 13 then solicited comments from interested persons. 14 Is that correct? 15 A. The typical administrativesque 16 process, yes. 17 Q. Okay. And the next sentence says: 18 "The thrust of most of the comments 19 was that many drugs could be purchased for 20 considerably less than 85 percent of AWP, 21 particularly multisourced drugs, while others were 22 not discounted."</p>

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